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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,732	09/26/2007	Michael D. Dake	13720-105071US2	3155
65989 7590 09/21/2009 KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003				
EXAMINER TONGUE, LAKIA J				
ART UNIT 1645		PAPER NUMBER		
NOTIFICATION DATE 09/21/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary

Application No.

10/591,732

Applicant(s)

DAKE ET AL.

Examiner

LAKIA J. TONGUE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-150 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 51-150 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 51-55, 64-74, 77-118, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent.

Group II, claim(s) 51, 54, 56, 57, 64-74, 77-118, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied to reduce or prevent an immune response.

Group III, claim(s) 51, 54 and 58, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is administered for prevention or reduction of symptoms associated with subjective or clinical hyperhidrosis.

Group IV, claim(s) 51, 54 and 59, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied for prevention or reduction of subjective or clinical dystonic contractions or dystonia.

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Group V, claim(s) 51, 54 and 60-63, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with muscle spasm.

Group VI, claim(s) 51, 75, 77-118, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with migraine headache.

Group VII, claim(s) 51, 76-118, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of acne.

Group VIII, claim(s) 51, 54, 119, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with mucous secretion.

Group IX, claim(s) 51, 54, 120, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of obesity or symptoms thereof.

Group X, claim(s) 51, 54, 121-123, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching

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groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of inflammation or symptoms thereof.

Group XI, claim(s) 51, 54, 124, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of snoring.

Group XII, claim(s) 51, 54, 125, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of cutaneous symptoms associated with diabetes.

Group XIII, claim(s) 51, 54, 126, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for improvement of wound healing.

Group XIV, claim(s) 51, 54, 127, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with autonomic nerve dysfunction.

Group XV, claim(s) 51, 54, 128, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with cerebral palsy.

Group XVI, claim(s) 51, 54, 129, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of

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the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with Hashimoto's thyroiditis.

Group XVII, claim(s) 51, 54, 130, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with mammary gland disorders.

Group XVIII, claim(s) 51, 54, 131, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for alteration of hair growth.

Group XIX, claim(s) 51, 54, 132, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with parathyroid disorders.

Group XX, claim(s) 51, 54, 133, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with movement disorders.

Group XXI, claim(s) 51, 54, 134, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with parkinson's disease.

Group XXII, claim(s) 51, 54, 135, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with tremors.

Group XXIII, claim(s) 51, 54, 136, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with epilepsy.

Group XXIV, claim(s) 51, 54, 137, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with inner ear disorder.

Group XXV, claim(s) 51, 54, 138, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with urologic disorders.

Group XXVI, claim(s) 51, 54, 139, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of other cholinergic-controlled secretions.

Group XXVII, claim(s) 51, 54, 140, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a

carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with neuropsychiatric disorders.

Group XXVIII, claim(s) 51, 54, 141, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with injured muscles.

Group XXIX, claim(s) 51, 54, 142, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with ear disorders.

Group XXX, claim(s) 51, 54, 143, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with cancer.

Group XXXI, claim(s) 51, 54, 144, 146, 149, 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with nerve entrapment disorders.

Group XXXII, claim(s) 51, 54, 145, 146, 149 and 150, drawn to a method of administering a botulinum toxin to a subject comprising topically applying to the skin or epithelium of the subject the botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent, wherein the botulinum is applied topically for prevention or reduction of symptoms associated with hypercalcemia.

The inventions listed as Groups I-XXXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XXXII appear to be a botulinum toxin in conjunction with an effective amount of a carrier comprising a polymeric backbone having attached positively charged branching groups, wherein the association between the carrier and the botulinum toxin is non-covalent and is topically applied to the skin or epithelium. However, the combination of Aoki et al. (WO 95/17904) in view of Paul et al. (Vaccine, 1998; 16(2/3): 188-195) renders the technical feature obvious. Aoki et al. disclose the use of botulinum toxin for relieving pain associated with muscle contractions, cholinergic secretions etc. (see abstract). Paul et al. disclose the use of a transdermal delivery system called transfersomes, which contains phosphatidylcholine, which is a branched fatty acid that has choline, which is a quaternary amine, and which is positively charged. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Aoki et al. by using the transdermal delivery system of Paul et al. to ultimately obtain a more efficient means of delivery because the delivery system can transport large macromolecules spontaneously through the skin in an immunologically active form and gives rise to specific antibody titers (see Paul-abstract). One would have had a reasonable expectation, barring evidence to the contrary, that the method would be effective for the delivery of botulinum toxin.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645

LJT
9/15/09